

Laurence D. King (SBN 206423)
KAPLAN FOX & KILSHEIMER LLP
350 Sansome Street, Suite 400
San Francisco, CA 94104
Telephone: 415-772-4700
Fax: 415-772-4707

Liaison Counsel for Plaintiffs

David George (*admitted pro hac vice*)
Robert J. Robbins (*admitted pro hac vice*)
COUGHLIN STOIA GELLER RUDMAN &
ROBBINS LLP
120 E. Palmetto Park Road, Suite 500
Boca Raton, FL 33432
Telephone: 561-750-3000
Fax: 561-750-3364

Joshua H. Vinik (*admitted pro hac vice*)
Lori G. Feldman (*admitted pro hac vice*)
Ross Brooks (*admitted pro hac vice*)
MILBERG LLP
One Pennsylvania Plaza
New York, NY 10119-0165
Telephone: 212-594-5300
Fax: 212-868-1229

Co-Lead Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

In re GILEAD SCIENCES SECURITIES
LITIGATION

This Document Relates To:
ALL ACTIONS.

) Case No. C-03-4999-SI
) CLASS ACTION
) PLAINTIFFS' MEMORANDUM OF
) POINTS AND AUTHORITIES IN
) OPPOSITION TO DEFENDANTS' MOTION
) TO DISMISS THE FIFTH CONSOLIDATED
) AMENDED COMPLAINT
)
) Date: October 9, 2009
) Time: 9:00 a.m.
) Dept.: Courtroom 10
) Judge: Honorable Susan Illston
)
) Trial Date: None set

TABLE OF CONTENTS

		Page
1		
2		
3	I. STATEMENT OF THE ISSUES.....	1
4	II. INTRODUCTION	1
5	III. PROCEDURAL HISTORY	3
6	IV. STATEMENT OF THE FACTS	4
7	V. ARGUMENT	7
8	A. Plaintiffs Satisfy the PSLRA and Sufficiently Describe Each of the Eight CWs.....	8
9	1. The CWs Allegations Establish the Pervasive Culture of Using Off-Label Marketing to Sell Viread During the Class Period	11
10	2. The Allegations of the CWs Establish the Pervasive Culture of Off-Label Marketing to Sell Viread Resulted in Off-Label Sales of Viread During the Class Period	13
11	3. There is Significant Evidence Corroborating the Testimony of the CWs Establishing Defendants' Use of Off-Label Sales of Viread During the Class Period	18
12		
13	B. Defendants' Arguments Regarding Perry, Bishofberger, Carraciolo and Lee Should Be Disregarded	19
14	1. This Court Has Already Found Grounds for Holding All of the Individual Defendants Liable.....	19
15	2. Defendants' Failure to Properly Seek Leave to Move For Reconsideration of Arguments Made in Prior Pleadings Violates N.D. Ca. Court Civil Local Civil Court Rule 7-9.	20
16		
17	C. Even Were the Court to Excuse Defendants' Violation of Local Rule 7-9 and Examine the Merits of Defendants' Arguments, Plaintiffs Still Prevail.....	21
18	1. Plaintiffs have Adequately Alleged a Primary Violation Against Each of the Moving Individual Defendants	21
19	2. Plaintiffs Adequately Pleaded Control Person Liability Under Section 20(a)	22
20		
21	VI. CONCLUSION.....	24
22		
23		
24		
25		
26		
27		
28	PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE FIFTH CONSOLIDATED AMENDED COMPLAINT CASE NO.C-03-4999-SI	

TABLE OF AUTHORITIES

FEDERAL CASES

<i>In re 21st Century Holding Co. Sec. Litig.</i> , No. 07-61057-civ, 2008 WL 5749572 (S.D. Fla. Nov. 7, 2008)	13
<i>Adaptive Broadband Sec. Litig.</i> , No. C01-1092 SC, 2002 WL 989478, at *19. (N.D. Cal. Apr. 2, 2002)	23
<i>In re Amtel Corp. Deriv. Litigation, C 06-4592 JF (HRL)</i> , 2008 U.S. Dist. LEXIS 91909 (N.C. Cal. June 25, 2008)	21
<i>Avery v. Correctional Office Thompson</i> , No. C-3-4233, RAW, 2009 U.S. Dist. LEXIS 22460 (N.D. Cal. Mar. 18, 2009)	20
<i>Basic, Inc. v. Levinson</i> , 485 U.S. 224 (1988)	18
<i>Batwin v. Occam Networks, Inc.</i> , CV 07-2750 CAS (SHx), 2008 U.S. Dist. LEXIS 52365 (C.D. Cal. July, 1 2008)	23
<i>Berson v. Applied Signal Tech., Inc.</i> , 527 F.3d 982 (9th Cir. 2008)	11 16
<i>Bielski v. Cabletron</i> , 311 F.3d 11 (1st Cir. 2002)	18, 19
<i>Californians for Disability Rights, Inc. v. Cal. Department of Transport</i> , No. C 06-5125 SBA, 2008 U.S. Dist. LEXIS 98929 (N.D. Cal. Nov. 24, 2008)	21
<i>Chapman v. Bay Municipal Court</i> , No. C-98-3641 VRW, 1998 U.S. Dist. LEXIS 20475, *2 (N.D. Cal. Dec. 31, 1998)	20
<i>In re Connectics Corp. Sec. Litig.</i> , 2008 U.S. Dist. LEXIS 62515 (N.D. Cal. Aug. 14, 2008)	7-8
<i>In re Cylink Sec. Litig.</i> , 178 F. Supp. 2d 1077 (N.D. Cal. 2009)	23
<i>In re Daou System Inc.</i> , 411 F.3d 1006 (9th Cir. 2005)	8, 9, 10, 11
<i>In re Gilead Sciences Sec. Litigation</i> , 536 F.3d 1049 (9th Cir. 2008)	<i>passim</i>
<i>Howard v. Everex System, Inc.</i> , 228 F.3d 1057 (9th Cir. 2000)	22, 23

1	<i>In re Immune Response,</i>	
	375 F. Supp. 2d 983 (S.D. Cal. 2005).....	17
2	<i>Ingle v. Circuit City,</i>	
3	408 F.3d 592 (9th Cir. 2005)	19
4	<i>Institutional Investors Group v. Avaya,</i>	
5	564 F.3d 242 (3d Cir. 2009)	9, 11
6	<i>In re Intern. Rectifier,</i>	
	CV 07-02544-JFW (VBKx), 2008 WL. 4555794 (C.D. Cal. May 23, 2008)	23
7	<i>Johnson v. Aljian,</i>	
8	394 F. Supp. 2d 1184 (C.D. Cal. 2004)	22
9	<i>In re Juniper Networks, Inc. Sec. Litig.,</i>	
10	542 F. Supp. 2d 1037 (N.D. Cal. 2008)	23
11	<i>Kaplan v. Rose,</i>	
	49 F.3d1366 (9th Cir. 1994)	23
12	<i>Lower Elwha Band of S'Klallams v. Lummi Indian Tribe,</i>	
13	235 F.3d 443 (9th Cir. 2000)	19
14	<i>Morris v. McGrath,</i>	
15	No. C 06-5015 SI (pr), 2008 U.S. Dist. LEXIS 91153 (N.C. Cal. Nov. 10, 2008)	20
16	<i>New York City Employees' Retirement Systems v. Berry,</i>	
	616 F. Supp. 2d 987 (N.D. Cal. 2009)	21
17	<i>No. 84 Employer-Teamster Joint Council Pension Fund v. America West Holding Corp.,</i>	
18	320 F.3d 920 (9th Cir. 2003)	17, 21, 22, 23
19	<i>Novak v. Kasaks,</i>	
20	216 F.3d 300 (2d Cir. 2000)	11
21	<i>Nursing Home Pension Fund v. Oracle Corp.,</i>	
	380 F.3d 1226 (9th Cir. 2004)	7, 9, 10, 11
22	<i>Paracor Finance, Inc. v. G. E. Capital Corp.,</i>	
23	96 F.3d 1151 (9th Cir. 1996)	23
24	<i>SEC v. Talbot,</i>	
25	530 F.3d 1085 (9th Cir. 2008)	22
26	<i>Sanchez v. Torres,</i>	
	No. C07-4174HRL, 2009 U.S. Dist. LEXIS 64037 (N.D. Cal. July 17, 2009).....	20
27		
28	PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE FIFTH CONSOLIDATED AMENDED COMPLAINT CASE NO.C-03-4999-SI	

1	<i>In re Silicon Graphics, Inc. Sec. Litig.</i> ,	
	183 F.3d 970 (9th Cir. 1999)	9-10
2	<i>South Ferry LP v. Killinger</i> ,	
3	542 F.3d 776 (9th Cir. 2008)	23
4	<i>Space System/Loral, Inc. v. Lockheed Martin Co.</i> ,	
5	No. C 96-3418 SI, 2003 U.S. Dist. LEXIS 26457 (N.D. Cal Oct. 7, 2003)	21
6	<i>Stoneridge Investment Partners, LLC v. Scientific-Atlanta</i> ,	
7	552 U.S. 148 128 S. Ct. 761 (2008).....	21
8	<i>Taylor v. Higgins</i> ,	
9	No. C 07-5295 MHP (pr), 2009 U.S. Dist. LEXIS 10448 (N.D. Cal. Jan. 29, 2009)	20
10	<i>Tellabs, Inc. v. Makor Issues & Rights, Ltd.</i> ,	
11	551 U.S. 308 (2007).....	10
12	<i>United States v. O'Hagan</i> ,	
13	521 U.S. 642 (1997).....	21, 22
14	<i>Zucco Partners, LLC v. Digimarc Corp.</i> ,	
15	552 F.3d 981 (9th Cir. 2009)	10, 13

MISCELLANEOUS

16	18B Wright, Miller & Cooper, <i>Federal Practice and Procedure: Jurisdiction</i> 2d § 4478,	
17	(2002).....	19
18	Civ. Local Rule 7-9(a)	20
19	Civ. Local Rule 7-9(c)	20

I. STATEMENT OF THE ISSUES

1. Whether the confidential witnesses (“CWs”) further support allegations of off-label sales of Viread during the Class Period in accordance with this Court’s June 3, 2009 Order (the “Order”).¹

II. INTRODUCTION

Plaintiffs’ Fifth Consolidated Amended Class Action Complaint dated July 10, 2009 (the “Fifth Amended Complaint”) satisfies each of the pleading requirements of the Private Securities Litigation Reform Act (the “PSLRA”), the Exchange Act, and the Federal Rules of Civil Procedure. This Court already found Plaintiffs adequately alleged sufficient facts to raise a strong inference that Defendants engaged in and had knowledge of Gilead Sciences, Inc.’s (“Gilead” or the “Company”) illegal off-label marketing of Viread and that the Fourth Amended Complaint (the “FAC”) sufficiently satisfied the pleading requirements of falsity and materiality as to Defendants’ omissions and misstatements. Order at 4; *see also*, October 11, 2005 Order (the “2005 Order”) at 9. Further, on appeal, the Ninth Circuit held the FAC satisfied the pleading requirements for loss causation. *See In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049 (9th Cir. 2008) (“*Gilead*”). This Court also held that Plaintiffs “adequately plead[ed] a basis for holding the individual defendants liable.” Order at 6. The only issue remaining at the pleading stage is whether Plaintiffs have established, through the use of CWs, sufficient support regarding allegations of off-label sales of Viread during the Class Period. *See id.* at 5.

The Fifth Amended Complaint details, among other things, how Defendants created and implemented a strategy of using off-label marketing to sell Viread during the Class Period and

¹ Defendants, in their Motion to Dismiss, raise two additional issues with regard to the liability of certain of the Individual Defendants under §10(b) and §20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”). As demonstrated herein, this Court previously rejected these arguments in the Order, and the Court should disregard them here. *See* 19-24 *infra*.

1 alleges that such sales occurred. The Fifth Amended Complaint goes further to plead that the
 2 off-label, fraudulent marketing scheme defined the culture of the Company. It sets forth how the
 3 fraud was accomplished, what it entailed, the product it involved, when it started, who
 4 participated in it or turned a blind eye toward it, the FDA's actions arising therefrom, and the
 5 percentage of Viread sold during the Class Period as a result of the off-label marketing.² These
 6 facts are established through, among other things, allegations attributed to eight CWs, six of
 7 whom were added to provide further support to existing allegations, as recommended in the
 8 Order. Order at 5. All of the CWs corroborate each other, as well as additional documentary
 9 evidence from the Food and Drug Administration (the "FDA"). In sum, the Fifth Amended
 10 Complaint unequivocally corrects the issues identified in the Order and demonstrates that
 11 Defendants' illegal off-label marketing of Viread resulted in off-label sales of Viread during the
 12 Class Period.

14 Defendants' agonizing dissection of the Plaintiffs' CWs in their motion to dismiss goes
 15 beyond the pleading requirements of this Circuit, ignores the corroborative nature of the CW
 16 allegations, and ignores the collective weight of the Fifth Amended Complaint's allegations.
 17 Defendants' motion also impermissibly resurrects arguments already rejected by this Court. In
 18 light of both the Ninth Circuit's and this Court's earlier holdings and because Plaintiffs have
 19 bolstered their factual allegations concerning off-label marketing and sales of Viread during the
 20 Class Period, Defendants' motion to dismiss (the "Motion" at ____") should be denied.³

23 ² Key details relating to Defendants' off-label marketing activities are set forth in the Fifth
 24 Amended Complaint at ¶74 through ¶223. Unless otherwise indicated, "¶____" refers to
 paragraphs of the Fifth Amended Complaint.

25 ³ Defendants have filed a new request for judicial notice. As Plaintiffs argued in their previous
 26 Response to Defendants' Request for Judicial Notice, though Federal Rule of Evidence § 201
 27 permits this Court to notice these documents for their contents, they may not be noticed for their
 truth.

III. PROCEDURAL HISTORY

Pursuant to the 2005 Order, Judge Jenkins dismissed Plaintiffs' Third Amended Complaint (the "TAC") for failure to adequately allege loss causation, but nevertheless found Plaintiffs "adequately alleged that Defendants engaged in an illegal off-label marketing scheme" and that it was "apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme." 2005 Order at 9. On December 2, 2005, Plaintiffs filed the FAC, which Judge Jenkins dismissed with prejudice on May 12, 2006, again finding Plaintiffs had not adequately alleged loss causation. On August 11, 2008 the Ninth Circuit reversed the District Court's dismissal and found Plaintiffs sufficiently alleged loss causation and economic loss. *See Gilead*, 536 F.3d at 1057-58. The case was remanded, and Defendants once again sought dismissal of the FAC.⁴ Pursuant to the Order, this Court found Plaintiffs adequately alleged falsity and materiality with regard to Defendants' omissions and misstatements, and that the FAC adequately pleaded a basis for holding the Individual Defendants liable. Order at 6. The Court, however, found the FAC deficient with regard to the reliability of statements made by two CWs described therein. The Court granted leave to amend the FAC to allow Plaintiffs to "add further support to allegations of off-label sales during the class period." *Id.* at 5. The Court stated Plaintiffs could add "additional confidential witnesses who allege that there were off-label sales of Viread during the class period and/or [provide] an explanation to the change in CW2's allegations on this point." *Id.* In the Fifth Amended Complaint, Plaintiffs do both. In addition to clarifying the circumstances in which CW2's allegations were made, the Fifth Amended Complaint includes detailed statements

⁴ On February 6, 2009, Defendants filed a Petition for Writ of Certiorari (the "Petition") to the Supreme Court of the United States seeking reversal of the Ninth Circuit's opinion. On April 20, 2009 the Petition was denied.

of an additional six CWs who provide further support to allegations of Defendants' fraudulent marketing scheme and concomitant off-label sale of Viread during the Class Period.⁵ Defendants once again move to dismiss the Fifth Amended Complaint, but, as indicated above, have not limited themselves to the sole issue defined and set forth in the Order.

IV. STATEMENT OF THE FACTS⁶

Plaintiffs allege Defendants engaged in a systemic, illegal off-label marketing scheme that resulted in off-label sales of Viread, one of the Company's drugs created for use in combination with other drugs for the treatment of HIV infection. ¶8. According to the CWs, this fraudulent scheme was executed from the top-down and defined the culture of the Company. ¶¶9, 51. Defendants, however, falsely reported that Viread sales were driven by strong demand, when, in fact, those sales were attributable in large part to the illegal off-label marketing of the drug. ¶7.

Plaintiffs demonstrated the off-label marketing and sales scheme in the FAC through several categories of factual allegations, among them the statements of two CWs.⁷ In light of the

⁵ To assist the Court in easily identifying the additional allegations set forth in the Fifth Amended Complaint, a redline comparison of the FAC and the Fifth Amended Complaint is attached hereto as Exhibit A.

⁶ Plaintiffs respectfully refer the Court to the Fifth Amended Complaint as well as the Ninth Circuit's opinion for a full recitation of the facts. *See Gilead*, 536 F.3d. at 1050-1054. In light of the several motions filed in this matter, all of which contain complete summaries of the factual allegations, and the narrow issue before the Court concerning the CWs, Plaintiffs primarily limit this factual statement to new CW allegations in the Fifth Amended Complaint.

⁷ The allegations included: (1) statements of two CWs; (2) a March 14, 2002 "Untitled FDA Letter," which documented Gilead's off-label marketing and stated Gilead "engaged in false and misleading promotional activities about the efficacy of Viread," improperly claimed Viread was "approved for a broad indication," and characterized Viread as a "miracle drug"; (3) a July 29th, 2003 "FDA Warning Letter," which stated Gilead's lies were so outrageous they created a new "intended use" for Viread, causing it to be misbranded, and that Gilead's repeated omissions and misrepresentations regarding Viread caused "significant public health and safety concerns"; (4) other anonymous sources described in the FAC, such as an "Infectious Disease Specialist in the Southeast United States," a "Medical Director of a large AIDS clinic in Washington, D.C.," and an "AIDS specialist from the Western United States," all of whom state that Gilead sales

Order, Plaintiffs bolstered their claims by adding allegations attributable to six additional CWs. See ¶¶49-73. These additional witnesses include two Gilead Therapeutic Specialists (CW6 and CW8); three witnesses who were both Therapeutic Specialists and Trainers during their tenure at Gilead (CW3, CW5 and CW7); and a CW who was a Gilead Medical Science Liaison and a Ph.D. (CW4).

The positions the CWs held while employed at Gilead afforded each an opportunity to see Defendants' scheme in action. The Therapeutic Specialists were responsible for promoting, marketing, and selling Viread with off-label information. ¶¶39, 42, 49. These employees, who had exposure to a variety of healthcare professionals, including physicians, nurses, social workers, and patients, had regular contact with and exposure to numerous Gilead executives and Regional Directors. *Id.* As Trainers, CW3 and CW5 were tasked with training Gilead's *entire* sales and marketing staff on how to improperly and illegally use off-label information to market and sell Viread. ¶81. Gilead used its Trainers to deliver the off-label message by developing training materials for HIV Therapeutic Specialists – both incumbent and incoming Gilead sales representatives. ¶¶50, 53, 60. The Medical Science Liaison, in addition to selling Viread, was responsible for presenting biased and off-label information during sales calls attended with Therapeutic Specialists. ¶¶57-58.

Several of the CWs describe their attendance and participation in numerous national and regional Gilead meetings wherein Gilead executives specifically discussed the off-label promotion of Viread. ¶¶39, 47, 52, 192. At these meetings, as well as at other times, Gilead provided the CWs with detailed information on Viread and told them, both overtly and covertly,

representatives marketed Viread for off-label purposes; (5) press releases discussing revenues and sales of Viread; and (6) the Individual Defendants' sales of stock during the Class Period. *See* Order at 2.

1 to use that information to aggressively promote and sell Viread. Much of that information,
2 which was used to sell Viread, had not been approved by the FDA for use in marketing and
3 promoting Viread. ¶8. It was off-label. Gilead executives provided this off-label information
4 despite knowing that off-label marketing violated FDA rules and regulations. ¶108. This
5 pervasive, covert strategy to market Viread off-label was executed from the top-down, defined
6 the culture of the Company, and was used to sell Viread.

7 The Fifth Amended Complaint clearly alleges that as a result of Defendants' illegal, off-
8 label marketing, a vast majority of Viread's sales – 75% to 95% – were off-label. ¶9. According
9 to CW1, 85% to 95% of his/her Viread Sales were a result of off-label marketing. ¶¶117, 205.
10 Similarly, 85% to 90% of CW2's Viread sales resulted from off-label marketing. ¶142. CW6
11 states that off-label marketing comprised "a core component of the Company's marketing and
12 sales for Viread." ¶68. Driven by Company management to improve sales numbers for
13 publication to a national marketplace, the sales staff sold Viread off-label "all the time" because
14 if they did not, they would be fired from Gilead. ¶71. In that regard, CW6 stated that easily 70%
15 of her/his sales were off-label. ¶¶71, 135, 170, 206, 218. Describing only two patient types,
16 CW7's sales of Viread were at least 20% completely off-label. ¶72. Further, both CW1 and
17 CW2 estimate that 85%-95% of all Viread sales during the Class Period were a direct result of
18 off-label marketing. ¶¶135, 218. CW3 and CW5, who both sold Viread and trained Gilead's
19 entire sales force to sell Viread with off-label information during the Class Period, each
20 confirmed that Defendants covert off-label marketing scheme resulted in a "large portion" of
21 Viread's sales being off-label. ¶¶49-55, 60-66.

22 According to CW3, the Company deliberately used its training department to deliver off-
23 label information to Gilead's sales force because the Company's marketing department could not
24 overtly tell the sales force to sell Viread off-label. ¶¶53, 149. In fact, there were weekly internal

1 Gilead meetings from at least 2002 until at least January 2005 (throughout the Class Period) at
 2 the Company's Foster City, California headquarters, to discuss the provision of off-label
 3 materials to the sales force. ¶¶54, 153. CW3 attended these meetings along with other
 4 marketing and training department heads, sales directors and James Meyers, Gilead's Vice-
 5 President of U.S. Sales. The upshot of these meetings was the Company intentionally provided
 6 its sales force with off-label information for the express purpose of illegal marketing and sale of
 7 Viread. *Id.* CW5, also a Company-wide trainer, confirmed the Company's strategy to market
 8 and sell Viread off-label was developed and driven from the top-executives, including Meyers.
 9 ¶60.

11 The allegations of the CWs, viewed in their entirety, document a pervasive culture of off-
 12 label marketing and sales at Gilead, executed from the top of the Company down. Simply put,
 13 Defendants implemented a strategy to boost sales by marketing and selling Viread off-label.
 14 This strategy began with, among other things, the Company's training department, flowed to its
 15 sales force, which utilized off-label materials to sell Viread, and succeeded when physicians
 16 prescribed Viread off-label. The deliberate strategy to market Viread off-label resulted in
 17 substantial off-label sales of Viread during the Class Period.

19 **V. ARGUMENT**

20 In considering a motion to dismiss, all "allegations of material fact made in the complaint
 21 are taken as true and construed in the light most favorable to the plaintiff." *Nursing Home*
 22 *Pension Fund v. Oracle Corp.*, 380 F.3d 1226, 1229 (9th Cir. 2004).⁸ "The question presented
 23 by a motion to dismiss is not whether the plaintiff will prevail in the action, but whether the
 24 plaintiff is entitled to offer evidence in support of the claim." *In re Connectics Corp. Sec. Litig.*,

26
 27 ⁸ Internal citations and footnotes are omitted, and emphasis is added, unless otherwise noted.

No. C-07-02940 SI, 2008 U.S. Dist. LEXIS 62515, at *8 (N.D. Cal. Aug. 14, 2008) (Illston, J.). Thus, “so long as the plaintiff alleges facts to support a theory that is not facially implausible, the court’s skepticism is best reserved for later stages of the proceedings when the plaintiff’s case can be rejected on evidentiary grounds.” *Gilead*, 536 F.3d at 1057. To state a claim under §10(b) and Rule10b-5, five elements must be established: “(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.” *In re Daou Sys. Inc.*, 411 F.3d 1006, 1014 (9th Cir. 2005).

After nearly six years of litigation on the pleadings, the only remaining deficiency identified by this Court in the FAC involved allegations attributed to the CWs concerning off-label sales of Viread. Order at 5. This deficiency centered on the fact that CW1 was not employed during the Class Period, and a perceived inconsistency in the allegations attributed to CW2. In its Order, the Court instructed “Plaintiffs may cure this deficiency by adding additional confidential witnesses who allege that there were off-label sales of Viread during the class period, and/or by providing an explanation of the change in CW2’s allegations on this point.” *Id.* Plaintiffs followed the Court’s directive and cured any lingering deficiency by adding specific allegations from six additional CWs and explaining the circumstances of CW2’s experience at Gilead. The Fifth Amended Complaint sets forth compelling further detail provided by eight reliable CWs to plainly establish there was a pervasive culture of off-label marketing and related sales of Viread during the Class Period.

A. Plaintiffs Satisfy the PSLRA and Sufficiently Describe Each of the Eight CWs

The Fifth Amended Complaint sets forth detail provided by eight CWs who have been described with a level of particularity far exceeding the standards set forth by the Ninth Circuit.

1 Plaintiffs described each witnesses' job description, responsibilities, and location and duration of
 2 employment. In some instances, Plaintiffs provided the witnesses' exact title and the name of
 3 the executive to whom the witness reported. *See Daou*, 411 F.3d at 1016 (PSLRA satisfied
 4 where CWs are described with specificity, especially where their job description and
 5 responsibilities are included); *see also Institutional Investors Group v. Avaya*, 564 F.3d 242, 263
 6 (3d Cir. 2009) (plaintiffs "adequately described the duration of each CWs employment, the time
 7 period during which the CW's acquired the relevant information, and how each CW had access
 8 to such information"). Plaintiffs provided all significant details, leaving out only the witnesses'
 9 identities.⁹

11 The level of detail set forth describing the CWs clearly "support[s] the probability that a
 12 person in the position occupied by the source would possess the information alleged." *Daou*, 411
 13 F.3d at 1015 (quoting *Oracle*, 380 F.3d at 1233); *see also In re Silicon Graphics, Inc. Sec.*

15
 16 ⁹ For example, CW3 worked at Gilead from 2000 until January of 2005 – throughout the Class
 17 Period. ¶49. From 2000 until 2002, CW3 worked as a Gilead Therapeutic Specialist in the
 18 Washington State area and reported to Regional Director David McCullough. *Id.* As such, CW3
 19 was responsible for selling Viread, among other drugs. *Id.* In 2002, CW3 was promoted to the
 20 role of Training Manager and worked in Gilead's Foster City, California headquarters where
 21 she/he worked with another training manager and reported to Meyers, the Company's Vice
 22 President of Sales. ¶50. As a Training Manager, CW3 was required to develop Company-wide
 23 training materials for *all* of Gilead's sales representatives for Viread. ¶¶50, 53. Indeed, CW3
 24 attended weekly internal Gilead meetings from at least 2002 until at least January 2005
 25 (throughout the Class Period) at the Company's headquarters. ¶¶54, 153. CW3 attended these
 26 meetings along with other marketing and training department heads, sales directors and Meyers.
 27 Attendees at these weekly meetings specifically discussed who made the decision to provide the
 sales force with off-label training materials for illegal marketing and sales of Viread. ¶¶54, 153.
 CW3 stated Gilead used its training department to deliver off-label information to Gilead's sales
 force for the purpose of selling Viread. The training department was used because the
 Company's marketing department could not overtly tell the sales force to sell Viread off-label.
 ¶¶53, 149. As another example, CW6 worked as a Therapeutic Specialist at Gilead from March
 2003 until January 2006 and was responsible for marketing HIV pharmaceuticals to hospitals,
 clinics and physicians in the Brooklyn, Queens and New York area. ¶67. CW6 recalled
 receiving and using off-label materials in sales presentations "all the time" and stated the
 Company's sales representatives were routinely provided with papers or studies supporting off-
 label use. ¶68. The use of these materials in sales presentations was prevalent for Viread. ¶¶68,
 169. In other words, CW6 and others sold Viread with off-label materials.

1 *Litig.*, 183 F.3d 970, 985 (9th Cir. 1999). Importantly, the allegations of the witnesses are
 2 substantially identical on all accounts, further supporting their reliability.¹⁰ These interlocking,
 3 corroborating statements are further buttressed by documentary evidence, including the Untitled
 4 FDA Letter and the FDA Warning Letter. Other anonymous sources, including HIV/AIDS
 5 practitioners interviewed through Plaintiffs' investigation further corroborate the CWs'
 6 experiences. The Fifth Amended Complaint contains both statements of CWs and "adequate
 7 corroborating details," and more than clears the pleading hurdles set forth in the PSLRA. *See*
 8 *Daou*, 411 F.3d at 1015.

10 Defendants pursue a "divide and conquer" attack on the Fifth Amended Complaint by
 11 dissecting each CW in isolation and manufacturing deficiencies in their allegations. But, this
 12 piecemeal approach cannot mask the staggering volume of corroborative allegations and
 13 evidence set forth the Fifth Amended Complaint. The CW allegations are delineated in clear and
 14 convincing detail and are corroborated by multiple sources that collectively establish
 15 Defendants' off-label sales of Viread. *Oracle*, 380 F.3d at 1224 (the allegations must be
 16 considered as a whole, even if individually lacking); *see also Tellabs, Inc. v. Makor Issues &*
 17 *Rights, Ltd.*, 551 U.S. 308 (2007). Further, Defendants call for a level of specificity well beyond
 18 what is required in this Circuit.¹¹ Based on the particularity with which each CW is described
 19

21 ¹⁰ Consistent with the Order, the Fifth Amended Complaint also includes an explanation
 22 addressing the Court's observations of statements attributed to CW2. Fifth Amended Complaint
 23 n.1. While the Defendants find the explanation unconvincing, Plaintiffs described the
 24 circumstances behind CW2's statements and addressed the Court's concerns head on. The Order
 25 directed Plaintiffs to add additional CWs "and/or" explain the change in CW2's allegations.
 26 (emphasis added). Plaintiffs did both, and Defendants' further examination of the credibility of
 27 CWs's clarified statements is irrelevant at the pleading stage.

25 ¹¹ Defendants repeatedly cite to *Zucco* throughout the Motion, which requires that a complaint
 26 provide "sufficient detail about a CWs' position within the company to provide a basis for
 27 attributing facts reported by that witness to that witness' personal knowledge." *Zucco Partners,*
LLC v. Digimarc Corp., 552 F.3d 981, 994 (9th Cir. 2009). As set forth herein, Plaintiffs have
 satisfied the required standard. Additionally, Plaintiffs have specifically addressed both of the

1 and the probability that the CWs possess knowledge as to their experiences at Gilead, including
 2 their first-hand knowledge of marketing and sales of Viread, Plaintiffs sufficiently met the
 3 standards for CWs under the PSLRA. Any possible dispute concerning the CW statements may
 4 not be resolved at this stage of the litigation and must, at least, await discovery. *Berson v.*
 5 *Applied Signal Tech., Inc.*, 527 F.3d 982 (9th Cir. 2008).¹²

6
 7 **1. The CWs Allegations Establish the Pervasive Culture of Using
 Off-Label Marketing to Sell Viread During the Class Period**

8 The Fifth Amended Complaint, which sets forth allegations of six additional CWs,
 9 demonstrates with increased detail the remarkable scope of Defendants' systemic plan to market
 10 and sell Viread off-label. ¶¶8, 81-193. According to the CWs, this fraudulent marketing strategy
 11 defined the very culture of the Company and was executed from the top-down. ¶¶51, 52, 60, 96,
 12 191, 218. The CWs report a widespread, deliberate Company-wide decision to market Viread
 13 for off-label indications which ensured that an enormous quantity of off-label sales would be
 14 accomplished. This strategy was effectuated through the creation and use of promotional
 15

16
 17 Court's concerns stemming from *Zucco* regarding clarification of CW2's statements and CW1's
 18 employment outside of the Class Period. Order at 4-5 n.4.

19 ¹² Moreover, in circumstances, as here, where there exists documentary evidence in further
 20 support of the allegations provided by CWs, personal sources of information may be relied upon
 21 if they are described with "sufficient particularity to support the probability that a person in the
 22 position occupied by the source would possess the information alleged." *Oracle*, 380 F.3d at
 23 1233. As long as plaintiffs describe the sources of their information in accordance with this
 24 standard and the complaint alleges "adequate corroborating details," a complaint will survive
 25 under the PSLRA. *Daou*, 411 F.3d at 1015. It is when there is a lack of documentary evidence
 26 that the level of detail describing the CWs is of heightened importance. *See Avaya*, 564 F.3d at
 27 242 (where plaintiff lacked documentary evidence court evaluated the detail provided by
 confidential sources, their basis of knowledge and reliability, the corroborative nature of other
 facts alleged, the coherence and plausibility of the allegations, and other similar indicia). Here,
 where there is both significant detail provided about and by the CWs, as well as documentary
 evidence from the FDA confirming the off-label marketing of Viread, Plaintiffs have undeniably
 satisfied the requirements of the PSLRA. *See Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)
 (a complaint will meet the pleading requirement of the PSLRA "by providing documentary
 evidence and/or a sufficient general description of the personal sources of the plaintiffs'
 beliefs").

1 materials, and included directives to sell Viread for off-label uses. These promotional materials
 2 were created by the Company's training department and distributed at numerous Company
 3 meetings during which sales and marketing personnel were instructed to promote and sell Viread
 4 for off-label uses. The CWs' allegations clearly demonstrate the pervasive culture of using off-
 5 label marketing to sell Viread during the Class Period.

6 To be sure, the Fifth Amended Complaint substantially expands on the breadth and depth
 7 of detail concerning the scope of Defendants' off-label marketing largely through the allegations
 8 of CW3,¹³ CW5,¹⁴ and CW4.¹⁵ The prior allegations had already "alleged sufficient facts to raise
 9

10
 11 ¹³ CW3 was both a Therapeutic Specialist and one of only two Company-wide Training
 12 Managers during the Class Period. ¶¶49-50. As a Training Manager, CW3 was tasked with
 13 developing training materials for HIV Therapeutic Specialists who were both incumbent and
 14 incoming Gilead sales representatives.¶50. This included writing sales materials for Therapeutic
 15 Specialists used in presentations (*i.e.*, sales calls) to doctors that included information approved
 16 by the FDA, as well as unapproved off-label information from recent conferences and studies.
 17 ¶52. According to CW3, these training materials, which contained a great deal of off-label
 18 information, were provided to the Company's sales force specifically for use in talking to doctors
 19 on whom they called. ¶¶53, 150. CW3 stated that the Company's sales force was deliberately
 20 being trained and encouraged – from the highest levels - to engage clients (*i.e.*, doctors and
 21 health practitioners) in off-label discussion for the purpose of selling Viread. *Id.* As set forth
 22 above, CW3 also attended weekly internal Gilead meetings at the Company's headquarters
 23 where the provision of these training materials to the Gilead sales force was discussed. ¶¶54,
 24 153. According to CW3, Defendants used Gilead's training department to deliver off-label
 25 information to Gilead's sales force because the Company's marketing department could not
 26 overtly tell the sales force to sell Viread off-label. ¶53.

19 ¹⁴ CW5 was also a Therapeutic Specialist and one of two Company-wide Training Managers at
 20 Gilead's headquarters. ¶60. CW5 stated there was a culture at Gilead that promoted and
 21 condoned off-label marketing of Viread throughout the Class Period. *Id.* This statement is the
 22 result of CW5's personal experiences at Gilead both "in the field" and in the training role where
 23 he/she was tasked with developing and distributing Company-wide training materials for the sale
 24 of Gilead pharmaceuticals, including Viread. *Id.* CW5 confirmed the use of off-label marketing
 25 materials by Therapeutic Specialists for use in promoting Viread and that use of the materials
 26 when meeting with doctors was encouraged. ¶61. For example, CW5 attended a slide
 27 presentation that was centered on the strategy to promote Viread off-label and included details
 about Gilead's efforts to use Medical Science Liaisons in a sales capacity to promote Viread off-
 label. ¶¶63-64. CW5 also acknowledged the use of briefing binders or "poster books" compiled
 for the Gilead sales force by the Company's trainers and sales managers for use in promoting
 Viread off-label, with the understanding that they were expected to promote the drug for off-
 label indications. ¶¶65, 159-61. According to CW5, Meyers was always telling her/him to
 promote the data that was coming out of conferences, which was the off-label, non-FDA
 approved data. ¶66.

a strong inference Defendants had knowledge of the company's off-label marketing scheme." Order at 4 n.4. When considered in conjunction with the additional, detailed and corroborated allegations by CW3, CW5 and CW4, Plaintiffs clearly establish the pervasive culture of off-label marketing, which was designed to sell Viread during the Class Period.¹⁶

2. The Allegations of the CWs Establish the Pervasive Culture of Off-Label Marketing to Sell Viread Resulted in Off-Label Sales of Viread During the Class Period

The fundamental purpose of the Defendants' illegal, off-label marketing scheme was to sell Viread. Given the fact that the Company's culture was defined by off-label marketing that emanated from its highest levels and was implemented through Company-wide training materials, and that the FDA twice chastised Gilead for its illegal conduct, the only logical conclusion, and only reasonable inference, is that off-label marketing resulted in off-label sales. ¶¶162-165.

¹⁵ CW4, a PhD, who was one of Gilead's first Medical Science Liaisons, stated that Gilead promoted off-label uses for Viread via presentations by Therapeutic Specialists to medical practitioners, as well as by encouraging the Medical Science Liaison staff to act in a sales capacity, which included presenting biased and unbalanced information about Viread. ¶¶56-57, 132. CW4's knowledge that Viread was promoted off-label was based on his/her participation in meetings the Therapeutic Specialists had with HIV treating physicians. *Id.* During the meetings Therapeutic Specialists utilized off-label information. According to CW4 "all of the [sales] reps" engaged in off-label detailing of Viread, and answered off-label questions without involving the Medical Science Liaison staff. ¶57

¹⁶ This Court did not "disregard CW1's allegations about his/her own experiences" even though he/or she was not employed during the Class Period. Order at 5. Similarly, allegations based on CW4's experiences may be considered by the Court even though CW4 left Gilead's employ just prior to the Class Period. *See also In re 21st Century Holding Co. Sec. Litig.*, No. 07-61057-civ, 2008 WL 5749572, at *7 (S.D. Fla. Nov. 7, 2008) (relying on allegations from pre-class period employee to sustain complaint when the source was described with sufficient particularity to support the probability that the source possessed the information alleged). Defendants reliance on *Zucco* to invalidate CW4's allegations is wrong. In *Zucco*, the Court found two CWs who were not employed during the class period unreliable, not because of their employment status, but because there was a lack of detail in one of the witness' allegations and the other witness had no personal knowledge as to the issue at hand, even while employed. *Zucco*, 552 F.3d at 996-97. The fact that CW4 left Gilead prior to the Class Period is irrelevant to his/her knowledge regarding the off-label marketing which the Fifth Amended Complaint alleges began in September 2001. ¶¶98-108.

Indeed, several CWs provide detailed allegations estimating, based on their experiences, the amount of off-label sales of Viread during the Class Period. The FAC set forth allegations from both CW1 and CW2 that 85%-95% of Viread's sales were caused by off-label marketing. ¶¶117, 135.¹⁷ CW1, who was responsible for marketing and selling Viread, was also a member of the Field Advisory Committee, a select group of Gilead sales and marketing staff that periodically met to discuss strategies for marketing and selling Viread. ¶¶40, 117. As such, CW1 was as an attendee at numerous meetings, including a Field Advisory Committee meeting attended by five other Therapeutic Specialists from other areas of the country, where CW1 learned first hand that the Therapeutic Specialists utilized off-label materials to promote Viread.¹⁸ ¶¶40, 117. CW2 also attended numerous national and regional Gilead meetings where Gilead executives specifically discussed the promotion of Viread and provided CW2 with detailed off label information. At these meetings CW2 was told, both overtly and covertly, to use the information to aggressively promote and sell Viread off-label. ¶47.

The Fifth Amended Complaint expands on the allegations set forth in the FAC. The existing allegations of CW1 and CW2 are corroborated by CW4, who stated that marketing and selling Viread off-label was always a key component of the Company's Viread strategy. ¶¶58, 93. CW6 further echoed this experience. CW6 who worked as a Therapeutic Specialist, from

¹⁷ The Fifth Amended Complaint contains the same allegations as the FAC in this regard. Therefore, Plaintiffs have cited to the paragraphs in the Fifth Amended Complaint that contain the appropriate references.

¹⁸ Defendants argue that CW1's allegations were and remain insufficient because CW1 was not employed during the Class Period. Motion at 10. However, this Court has already held CW1's allegations are valid and did not "discount CW1's allegations about his/her own experiences, such as sales prior to the [C]lass [P]eriod, or meetings that CW1 attended." Order at 5. Instead, the Court allowed Plaintiffs to add further support to the allegations of off-label sales during the Class Period. *Id.* In light of the consistent, corroborating allegations provided by additional CWs, the statements of CW1 are reliable and offer additional credence to allegations demonstrating Defendants off-label marketing scheme resulted in off-label sales of Viread.

1 March 2003 until January 2006, recalled receiving and using off-label materials “all the time” in
 2 sales presentations and stated the Company’s sales representatives were routinely provided with
 3 papers or studies supporting one or another off label use. ¶68. Importantly, CW6’s experiences
 4 also corroborate those of CW5 in that he/she confirmed the use of off-label materials being
 5 included in a binder distributed to sales representatives. ¶¶65, 69, 159-161. According to CW6,
 6 easily 70% of his/her Viread sales were attributable to off-label, treatment naïve patients. ¶¶71,
 7 117, 120. CW6 stated that if Therapeutic Specialists did not sell Viread as a first line-therapy,
 8 they would be fired. ¶¶71, 120. 169.

10 Similarly, CW7, a former Therapeutic Specialist and Trainer for Gilead in Dallas, who
 11 was with the Company from prior to 2002 until approximately 2006, estimated that 10% of
 12 his/her total Viread sales were off-label to physicians treating Hepatitis B infected patients and
 13 that 10% of his/her total Viread sales were off-label in the pediatric population. ¶72. Therefore,
 14 20% of CW7’s sales of Viread were completely off-label and these sales represented only two
 15 segments of patients to whom Viread was marketed.¹⁹ According to CW7, Company sales
 16 representatives were feeling pressure to engage in off-label marketing to boost their sales. *Id.*

18 The quantification of actual off-label sales of Viread made by CW1, CW2, CW6 and
 19 CW7 is supported and bolstered by the allegations of CW3, CW4, CW5 and CW8, all of whom
 20 have personal knowledge of Gilead’s training and marketing materials used to promote the off-
 21 label sales of Viread. The interlocking, corroborating allegations of the CWs paint an
 22 overwhelming picture of the pervasive culture of the off-label marketing, promotion and sale of
 23

24
 25 ¹⁹ Defendants argue there is no basis for extrapolating CW6’s off-label sales of Viread to
 26 establish the total off-label sales of Viread, but it is no coincidence that extrapolation of said
 27 amount does verify the allegations of CW1, CW2 and CW6 and therefore, it is reasonable to
 infer that 75%-95% of Viread’s sales during the Class Period were the result of off-label
 marketing. *See, e.g.*, ¶206.

1 Viread. Indeed, the fundamental purpose of off-label training and marketing was solely to boost
2 sales of the drug.

3 The quantification of off-label sales alleged by the CWs is supported further still by the
4 fact that all of the CWs collectively described the significant details of Gilead's systematic use
5 and presentation of off-label information to market and sell Viread, and all confirm the stunning
6 impact the use of that off-label information had on Viread sales. ¶¶191. The CWs recall various
7 meetings where slides, posters and promotional materials that included off-label illegal
8 information were deliberately provided by the Company's training department to the entire sales
9 force for use in illegal marketing and sales activities. ¶¶84-90, 95-113, 119. This promotional
10 material distributed by the Company's training department and the off-label sales tactics learned
11 in the meetings were used by Gilead's sales people, as required, to promote Viread. ¶¶116, 117.
12 The off-label promotion and marketing of Viread had a sole purpose – to sell Viread. Gilead
13 used off-label marketing to sell more Viread as physicians prescribed more of it, often for
14 purposes other than those approved by the FDA, and often based on Gilead's lies about the true
15 safety profile of the drug. ¶¶141, 158-59. Thus, Defendants provided so much off-label material
16 and were so forceful in instructing sales representatives to utilize off-label information that
17 almost all of Viread's sales – 75% to 95% – arose from off-label promotion. ¶¶141-65.

20 The CW allegations are based on their own experiences within the Company and their
21 personal knowledge of Defendants' knowing use of illegal sales tactics and the off-label
22 marketing scheme. Defendants quibble that CW3 and CW5 do not have personal knowledge as
23 to the sales of Viread because they were involved in training the sales personnel instead of
24 personally making sales and, as to CW8, that he/she did not allege personally making any sales.
25 Any number of employees, however, may be in a position to infer the sales of Viread. *See*
26 *Berson*, 527 F.3d at 985 (CWs who were engineers or technical editors would be in a position to

1 have knowledge of company setbacks even though they were not managers). Further, it is
 2 entirely plausible that each of the CWs described in the Fifth Amended Complaint would know,
 3 or could reasonably deduce, that the Company made such sales. *Id.* In fact, the CW allegations
 4 establish each of them were in a position to know or reasonably infer that the off-label marketing
 5 each of them personally participated in, assisted or witnessed resulted in off-label sales of Viread
 6 during the Class Period. As noted above, CW3 and CW5 trained Gilead's entire sales force.
 7 Specifically, they were charged with the task of developing and distributing the training
 8 materials that provided off-label marketing strategies directly to the Company's entire sales force
 9 with instructions to promote Viread off-label. ¶¶50, 53, 60. It is unreasonable to infer that
 10 Gilead would hire people to create off-label marketing materials, instruct its sales force to use
 11 them, but that such activities would not result in off-label sales. Further, during their
 12 employment with Gilead, CW3, CW4 and CW5 each personally promoted and/or witnessed the
 13 off-label promotion of Viread during sales calls. ¶¶51, 58, 60. In addition, all of the CWs
 14 attended Company meetings where off-label marketing, promotion and sales were discussed and
 15 encouraged. Finally, CW1, CW2 CW6 and CW7 actually sold Viread off-label during the Class
 16 Period. Defendants further attack the allegations of CW6, CW7 and CW8, arguing their sales
 17 were not "significant sales." But, the Court did not require Plaintiff to demonstrate sales that rise
 18 to such an arbitrary standard. Instead, the Order only required Plaintiffs "add further support to
 19 allegations of off label sales during the class period." Order at 5.

22 In any event, the proper standard by which to measure sales is whether they would be
 23 material to an investor, specifically whether there is a "substantial likelihood that a reasonable
 24 investor would consider it important in his or her decision making." *In re Immune Response*,
 25 375 F. Supp. 2d 983, 1021 (S.D. Cal. 2005). Further, materiality determinations are particularly
 26 suited for the trier of fact, *No. 84 Employer-Teamsters v. Am. West*, 320 F.3d 920, 934 (9th Cir.

2003); *see also Basic, Inc. v. Levinson*, 485 U.S. 224, 240 (1988). These are not mere conclusions, but an accumulated amount of specific details describing precisely how Defendants effectuated the fraudulent scheme of off-label marketing which resulted in off-label sales of Viread. *See Bielski v. Cabletron*, 311 F.3d 11, 30 (1st Cir. 2002). Based on these corroborating allegations and the pervasive culture of off-label marketing, which permeated the Company, it is entirely reasonable to conclude that the off-label promotion and marketing resulted in off-label sales of Viread.

3. There is Significant Evidence Corroborating the Testimony of the CWs Establishing Defendants' Use of Off-Label Sales of Viread During the Class Period

Significant documentary evidence corroborates the CW allegations. The Untitled FDA Letter and the FDA Warning Letter substantiate the allegations of all of the CWs and, in and of themselves, are sufficient to establish Defendants' knowledge of the off-label marketing scheme and the sales effectuated therefrom.²⁰ The Fifth Amended Complaint also relies upon the detailed statements of several medical practitioners with firsthand experience of Defendants' off-label marketing scheme, all of which further substantiate the CW allegations.²¹ The sum of this corroborative evidence further bolsters the reliability of the CWs, and satisfies this Court's directive to provide standard of reliability for CWs. Therefore, based upon the substantially identical allegations of the CWs and the significant volume of corroborating evidence delineated

²⁰ The FDA Warning letter unequivocally condemned Gilead's off-label marketing practices and ordered Gilead to stop. ¶¶78, 91-121, 125-33. The FDA Warning Letter also stated Gilead's lies were so outrageous that they had created a new "intended use" for Viread causing it to be misbranded, and that Gilead's repeated omissions and misrepresentations regarding Viread caused "significant public health and safety concerns." ¶¶128-29.

²¹ *See* ¶217 (AIDS-specialist received unsolicited off-label data from Gilead); ¶214 (infectious disease specialists with a large AIDS practice received unsolicited off-label advice on using Viread and wrote prescriptions as a result); ¶216 (medical director of a large AIDS clinic wrote prescriptions for Viread based on false and misleading sales pitches concerning safety profile).

1 in the Fifth Amended Complaint, the CWs provide further support to allegations of off-label
 2 sales during the Class Period as required by the Order. Plaintiffs meet the pleading requirements
 3 of the PSLRA, and the Motion should be denied.

4 **B. Defendants' Arguments Regarding Perry, Bishofberger, Carraciolo and Lee**
 5 **Should Be Disregarded**

6 **1. This Court Has Already Found Grounds for Holding All of the**
 7 **Individual Defendants Liable**

8 In the Order, this Court specifically held that "that the FAC adequately pleads a basis for
 9 holding the individual defendants liable."²² Order at 5-7. The determination of these issues in
 10 the Order are law of the case.²³ Incredibly, Defendants argue again that "Plaintiffs fail to
 11 adequately allege that Defendants Perry, Bischofberger, Carraciolo, and Lee²⁴ made any false
 12 statements of substantially participated in the preparation of any false statements." Motion at 19.
 13 Defendants also argue that "Plaintiffs have not pleaded sufficient facts to establish control person
 14 liability." *Id.* at 23. Defendants unsuccessfully made both of these very same arguments in their
 15 previous motion to dismiss.²⁵ The Court has already rejected the Moving Individual Defendants'
 16 arguments once; it should disregard them now.²⁶

18
 19 ²² The Court held that it "is not persuaded by the other contentions raised in defendants' motion
 to dismiss." Order at 5.

20 ²³ See *Ingle v. Circuit City*, 408 F.3d 592, 594 (9th Cir. 2005) ("Under the law of the case
 21 doctrine, 'a court is generally precluded from reconsidering an issue previously decided by the
 22 same court, or a higher court in the identical case.'") quoting *Lower Elwha Band of S'Klallams v.*
 23 *Lummi Indian Tribe*, 235 F.3d 443, 452 (9th Cir. 2000). The doctrine's purpose is to "maintain
 consistency and avoid reconsideration of matters once decided during the course of a single
 continuing lawsuit." 18B Wright, Miller & Cooper, *Federal Practice and Procedure:*
Jurisdiction 2d § 4478, at 637-38 (2002).

24 ²⁴ Defendants Perry, Bischofberger, Carraciolo, and Lee shall be referred to herein as the
 "Moving Individual Defendants."

25 ²⁵ See Dkt. #211 at 25 ("If the Court were to decide that the FAC adequately pleads scienter and
 26 falsity, the claims against defendants Perry, Biscofberger (sic), Carraciola, and Lee should
 27 nevertheless be dismissed because Plaintiffs do not attribute any allegedly false statements to
 these individuals, nor do Plaintiffs allege that they signed any of the relevant SEC filings.
 (Citation omitted.) In fact, the FAC does not contain any allegations as to the role any of these

**2. Defendants' Failure to Properly Seek Leave to Move For
Reconsideration of Arguments Made in Prior Pleadings
Violates N.D. Ca. Civil Local Rule 7-9.**

Local Rule 7-9(a) provides that: "No party may notice a motion for reconsideration without first obtaining leave of Court to file the motion." Civil L.R. 7-9(a); *see also Sanchez v. Torres*, No. C07-4174HRL, 2009 U.S. Dist. LEXIS 64037, at *10 (N.D. Cal. July 17, 2009); *Avery v. Corr. Office Thompson*, No. C-3-4233 RMW, 2009 U.S. Dist. LEXIS 22460, at *2 (N.D. Cal. Mar. 18, 2009). Because Defendants failed to seek leave of Court in violation of Local Rule 7-9(a), their backhanded motion for reconsideration should not be considered. *See Morris v. McGrath*, No. C 06-5015 SI (pr), 2008 U.S. Dist. LEXIS 91153, at *3 (N.C. Cal. Nov. 10, 2008) (Illston, J.) ("To seek reconsideration of an interlocutory order. . . defendants had to comply with Civil L.R. 7-9(a)");²⁷ *Taylor v. Higgins*, No. C 07-5295 MHP (pr), 2009 U.S. Dist. LEXIS 10448, at *11 (N.D. Cal. Jan. 29, 2009) (same). Defendants have also violated Local Rule 7-9(c), which prohibits repetition of an argument previously made, and which holds such repetition to be sanctionable. Civil L.R. 7-9(c); *Chapman v. Bay Mun. Court*, No. C-98-3641 VRW, 1998 U.S. Dist. LEXIS 20475, at *2 (N.D. Cal. Dec. 31, 1998) ("A party seeking leave to file a motion to reconsider may not repeat arguments she has previously made to support her

defendants played, if any, in drafting or disseminating any of the statements."); *Id.* at 23 ("Plaintiffs have not pleaded facts to establish control person liability.").

²⁶ Defendants boldly ignore this Court's ruling that it "is not persuaded by the other contentions raised in defendants' motion to dismiss." Order at 5. Defendants purport to carve the Moving Individual Defendants out of the Court's ruling, but the Court applied no such limitation. *See* Motion at 20, n.5. To the extent Defendants were confused about the Court's prior holding, they could have raised such concerns at the case management conference on July 21, 2009, or moved for clarification, rather than trying to improperly resurrect issues already decided.

²⁷ In *Morris*, a case decided by this Court, defendants also moved improperly to dismiss again on grounds previously found lacking, rather than seeking leave to make a motion for reconsideration. *Morris*, 2008 U.S. Dist. LEXIS 91153, *2 ("The motion seeks to have the court revisit a decision already made, as the court had decided that the complaint *did* state a claim upon which relief may be granted."). (Emphasis in original).

position and such prohibited repetition is sanctionable.”). Defendants’ brazen disregard for the local rules of this Court should not be permitted.²⁸

C. Even Were the Court to Excuse Defendants’ Violation of Local Rule 7-9 and Examine the Merits of Defendants’ Arguments, Plaintiffs Still Prevail

1. Plaintiffs have Adequately Alleged a Primary Violation Against Each of the Moving Individual Defendants

The Individual Moving Defendants assert Plaintiffs’ §10(b) claims should be dismissed because Plaintiffs do not allege that those Defendants made any misstatements. *See, e.g.*, Motion at 19-20. However, as the Supreme Court held in *Stoneridge Investment Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148 128 S.Ct. 761 (2008), “to suggest there must be a specific oral or written statement before there could be liability under § 10(b) or Rule 10b-5 [] would be erroneous.” *Id.* at 769. This is true because “[co]nduct itself can be deceptive.” *Id.*; *New York City Employees’ Ret. Sys. v. Berry*, 616 F. Supp. 2d 987, 995 (N.D. Cal. 2009); (quoting *Stoneridge*, 552 U.S. 148); *In re Amtel Corp. Deriv. Litig.*, C 06-4592 JF (HRL), 2008 U.S. Dist. LEXIS 91909, at *2 (N.C. Cal. June 25, 2008). With respect to the commission of a deceptive act, the Supreme Court has held that the act of insider trading gives rise to a Section 10(b) claim. *See United States v. O’Hagan*, 521 U.S. 642, 652 (1997). Likewise, in *No. 84 Employer-Teamster Joint Council Pension Fund v. Am. West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003), the Ninth Circuit held that the fact of a defendant’s not having made “any of the allegedly

²⁸ Even setting aside Defendants’ procedural violations of Local Rule 7-9, their arguments must fail because they could not have satisfied any of the necessary grounds for reconsideration. Local Rule 7-9(b) provides that a “party may make a motion to the Court to reconsider its ruling if it can show that (1) a material difference in law or facts now exists than that which existed when the Court rendered its judgment, (2) there are new facts or a material change in the applicable law, or (3) there was a ‘manifest failure’ of the Court to consider facts previously presented for consideration.” *Space Sys. Loral, Inc. v. Lockheed Martin Co.*, No. C 96-3418 SI, 2003 U.S. Dist. LEXIS 26457, at *3 (N.D. Cal. Oct. 7, 2003) (Illston, J.); *Californians for Disability Rights, Inc. v. Cal. Dept. of Transp.*, No. C 06-5125 SBA, 2008 U.S. Dist. LEXIS 98929, at *5 (N.D. Cal. Nov. 24, 2008). Defendants satisfy none of these requirements.

misleading statements does not shield them from liability” because “[i]ndividuals or corporations that engage in insider trading can be held liable under Section 10(b) and Rule 10b-5.” *Id.* at 937.²⁹

In light of the Court’s prior ruling, and the fact that Plaintiffs allege each of the Moving Individual Defendants, as well as the non-moving ones, engaged in insider trading, Plaintiffs have clearly alleged a primary violation of §10(b) against the Moving Individual Defendants. *See Johnson v. Aljian*, 394 F. Supp. 2d 1184, 1196 (C.D. Cal. 2004) (Rule 10b-5 is violated by a corporate insider’s buying or selling securities on the basis of material nonpublic information).

2. Plaintiffs Adequately Pleaded Control Person Liability Under Section 20(a)

In the Ninth Circuit, to “prove a prima facie case under Section 20(a), a plaintiff must prove: (1) a primary violation of federal securities law and (2) that the defendant exercised actual power or control over a primary violator.” *Am. West*, 320 F.3d at 945. It is not necessary to show actual participation or the exercise of power. *Id.*; *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1065 (9th Cir. 2000).³⁰ Here, Plaintiffs adequately allege a primary violation under §10(b). Moreover, the additional determination of whether a defendant is a control person is not typically decided on a motion to dismiss because “[w]hether [each of the Individual Defendants is] a controlling person is an intensely factual question, involving scrutiny of the defendant’s participation in the day-to-day affairs of the corporation and the defendant’s power to control

²⁹ *See also SEC v. Talbot*, 530 F.3d 1085, 1090-91(9th Cir. 2008) (“Traditionally, § 10(b) and Rule 10b-5 have reached [] what is termed ‘classical’ insider trading. “Under the ‘traditional’ or ‘classical theory’ of insider trading liability, § 10(b) and Rule 10b-5 are violated when a corporate insider trades in the securities of his corporation on the basis of material nonpublic information.”) (quoting *O’Hagan*, 521 U.S. at 651-52).

³⁰ Plaintiffs need only set forth a prima facie case, but Defendants ask that the Court go further, asserting that “Plaintiffs have not pleaded facts sufficient to *establish* control person liability (Motion at 23), and that Plaintiffs “failed to allege specific facts *demonstrating* that any individual defendant controlled a primary violator.” *Id.* at 24.

1 corporate actions.” *Am. West*, 320 F.3d at 94 (quoting *Kaplan v. Rose*, 49 F.3d1366, 1389 (9th
2 Cir. 1994)5; *see also Paracor Fin., Inc. v. G. E. Capital Corp.*, 96 F.3d 1151, 1161 (9th Cir.
3 1996).

4 Defendants attack the specificity of Plaintiffs’ control person allegations. Motion at 23.
5 Yet, a claim under §20(a) need not meet this level of specificity because it “must be pleaded in
6 accordance with Fed. R. Civ. P. 8(a)(2), requiring that the plaintiff provide a ‘short and plain
7 statement of the claim showing that the pleader is entitled to relief.” *Batwin v. Occam Networks,*
8 *Inc.*, CV 07-2750 CAS (SHx), 2008 U.S. Dist. LEXIS 52365, at *74 (C.D. Cal. July, 1 2008).
9 Plaintiffs have done so here by setting forth each of the Individual Defendants’ high-level
10 positions and describing their significance.³¹ *See In re Juniper Networks, Inc. Sec. Litig.*, 542 F.
11 Supp.2d 1037, 1054 (N.D. Cal. 2008). *In re Cylink Sec. Litig.*, 178 F. Supp. 2d 1077, 1089
12 (N.D. Cal. 2009) (“plaintiffs need not allege that the individual defendants actually participated
13 in the wrongful conduct or exercised actual power to be derivatively liable under section 20(a);”
14 rather, individual defendants were control persons because “by virtue of their executive and
15 managerial positions [they] had the power to control and influence [defendant corporation]
16 which they exercised”).³²
17
18

19
20 ³¹ *See* ¶¶ 23-28, 296-97. The fact that each of the Moving Individual Defendants held important
21 positions at the Company is sufficient in and of itself at the pleading stage to allege control
22 person liability. *See In re Adaptive Broadband Sec. Litig.*, No. C01-1092 SC, 2002 WL 989478,
23 at *19. (N.D. Cal. Apr. 2, 2002). Additionally, the Court previously held “that the FAC
24 adequately pleads a basis for holding the individual defendants liable,” and cited *South Ferry LP*
v. Killinger, 542 F.3d 776, 782 (9th Cir. 2008), which presupposes that the Individual
Defendants’ role in managing the Company was significant enough to hold them primarily liable
for a Section 10(b) violation.

25 ³² *In re Intern. Rectifier*, CV 07-02544-JFW (VBKx), 2008 WL 4555794 (C.D. Cal. May 23,
2008), cited by Defendants, is easily distinguishable. In *Intern. Rectifier*, “Plaintiffs have not
26 alleged that Grant had authority over the preparation of the financial statements or press releases
27 or conference calls containing the misleading statements-just that he had the authority or control
over global sales and marketing.” *Id.*, at *22. Here, as stated above, Plaintiffs did in fact make
such allegations. Moreover, Defendants’ reliance on *Howard*, 228 F.3d at 1066, for the

1 Considering the Order and the fact that Plaintiffs have adequately alleged a primary
 2 violation of §10(b), and that each of the Moving Individual Defendants had the power to
 3 influence and control Gilead, the Fifth Amended Complaint sufficiently pleads control person
 4 liability under §20(a).

5 **VI. CONCLUSION**

6 For all the foregoing reasons, Plaintiffs respectfully request that Defendants' motion be
 7 denied in its entirety.

8 DATED: September 4, 2009

KAPLAN FOX & KILSHEIMER LLP

11 /s/ LAURENCE D. KING
 12 LAURENCE D. KING

13 350 Sansome Street, Suite 400
 14 San Francisco, CA 94104
 15 Telephone: 415-772-4700
 16 Fax: 415-772-4707
 17 email: lking@kaplanfox.com

18 ***Liaison Counsel for Plaintiffs***

19 Joshua H. Vinik (*admitted pro hac vice*)
 20 jvinik@milberg.com
 21 Lori G. Feldman (*admitted pro hac vice*)
 22 lfeldman@milberg.com
 23 Ross Brooks (*admitted pro hac vice*)
 24 rbrooks@milberg.com
 25 MILBERG LLP
 26 One Pennsylvania Plaza
 27 New York, NY 10119-0165
 28 Telephone: 212-594-5300
 Fax: 212-868-1229

25 proposition that Plaintiffs' Section 20(a) claim should be dismissed because "Plaintiffs have
 26 provided no specific allegations regarding who had control over Gilead's press releases and
 27 financial statements" should be disregarded because *Howard* sets forth a summary judgment, not
 a motion to dismiss standard. Motion at 23.

David J. George (*admitted pro hac vice*)
dgeorge@csgrr.com
Robert J. Robbins (*admitted pro hac vice*)
rrobbins@csgrr.com
Holly Kimmel (*admitted pro hac vice*)
hkimmel@csgrr.com
COUGHLIN STOIA GELLER RUDMAN &
ROBBINS LLP
120 E. Palmetto Park Road, Suite 500
Boca Raton, FL 33432
Telephone: 561-750-3000
Fax: 561-750-3364

Co-Lead Counsel for Plaintiffs